

REMARKS**I. Introduction**

Claims 7 and 9 to 13 are pending in the present application. In view of the foregoing amendments and the following remarks, it is respectfully submitted that all of the presently pending claims are allowable, and reconsideration is respectfully requested.

Applicants note with appreciation the acknowledgment of the claim for foreign priority and the indication that all certified copies of the priority documents have been received.

Applicants notes that the Final Office Action does not contain an initialed copy of the Information Disclosure Statement that was previously filed on August 10, 2002 and resubmitted on March 18, 2003. Applicants respectfully request, in light of the resubmission of the Information Disclosure Statement along with copies of all listed references on March 18, 2003, that the references listed therein be considered by the Examiner and that an initialed copy of the Information Disclosure Statement be provided in the next Office Action.

II. Rejection of Claims 7, 12 and 13 Under 35 U.S.C. § 102(e)

Claims 7, 12 and 13 were rejected under 35 U.S.C. 102(e) as anticipated by U.S. Patent No. 5,744,031 ("Bene"). Applicants respectfully submit that Bene does not anticipate the present claims for the following reasons.

Claim 7 relates to a dialysis machine. Claim 7 recites that the dialysis machine includes a dialyzer and a semipermeable membrane dividing the dialyzer into a blood chamber and a dialysis fluid chamber, the blood chamber having an inlet and an outlet, and the dialysis fluid chamber having an inlet and an outlet. Claim 7 also recites that the dialysis machine includes an arterial blood line connected to the inlet of the blood chamber, and a venous blood line connected to the outlet of the blood chamber. Claim 7 also recites that the dialysis machine includes a dialysis fluid inlet line connected to the inlet of the dialysis fluid chamber, and a dialysis fluid outlet line connected to the outlet of the dialysis fluid chamber. Claim 7 also recites that the dialysis machine includes a device for determining at least one of a blood flow rate Q_b through the blood chamber, a dialysis fluid flow rate Q_d through the dialysis fluid chamber, and an ultrafiltration rate Q_f . In addition, claim 7 has been amended herein without prejudice to recite that the dialysis

machine includes means for determining in a first step at least one of a clearance and a dialysance during a dialysis treatment, at the at least one of the blood flow rate Q_b , the dialysis fluid flow rate Q_d , and the ultrafiltration rate Q_f determined by the first device. Claim 7 has been amended herein without prejudice to recite that the means for determining at least one of a clearance and a dialysance is a computer unit which is configured to determine in a subsequent step at least one of the clearance and the dialysance at the at least one of a blood flow rate $Q_b(t)$, a dialysis fluid flow rate $Q_d(t)$, and an ultrafiltration rate $Q_f(t)$, on the basis of, and without requiring additional measurements of, the at least one of the clearance and a dialysance initially determined at the at least one of a predetermined blood flow rate Q_b , a predetermined dialysis fluid flow rate Q_d , and a predetermined ultrafiltration rate Q_f . Support for these amendments can be found at page 5, lines 4 to 6 of the Specification which states that "only a single measurement [i.e., an initial measurement] is necessary to be able to monitor the course of the clearance and/or dialysance over time." Emphasis added.

Bene purports to relate to an artificial kidney that includes measurement structure for measuring at least one physical characteristic of a fresh dialysis liquid and of used liquid. According to Bene, the measurement structure are disposed in a line portion common to a branch circuit to the feeder line of fresh dialysis liquid and to a branch circuit to the discharge line for the used liquid. Bene states that an occluding structure permits the liquid to circulate exclusively in one or the other branch circuit, and that, due to this arrangement, it is possible to obtain the value of the physical characteristics of a patient's blood by calculation as frequently as desired, and to adjust the operation of the kidney permanently to a therapeutic objective set by the physician.

The Final Office Action contends that "Bene discloses a dialysis system comprising a dialyzer (1) divided by a semipermeable membrane (4) into a blood chamber (2) and a dialysis chamber (3) [and that the] blood chamber has an inlet connected to an arterial blood line (5) and an outlet connected to a venous blood line (7)." Final Office Action at p. 2. The Final Office Action also contends that "[s]ince the claim is open-ended (i.e. 'comprising'), the venous line is seen to be connected to the blood outlet regardless of the intervening bubble trap [and since] the claim does not require that the venous line be 'directly connected' to the outlet [] this limitation is met." Final Office Action at pp. 2 to 3. The Final Office Action also

states that "[t]he dialysis chamber has an inlet connected to a dialysis fluid inlet line (13) and an outlet connected to a dialysis fluid outlet line (29) [, a] blood pump (6) is connected to the arterial, a first dialysis fluid pump (15) is connected to the dialysis Inlet line and a second dialysis fluid pump (22) is connected to the dialysis fluid outlet line [and] flow meters (24/25) measure the inflow and outflow rates of the dialysis fluid." Final Office Action at p. 3. The Final Office Action further contends that "Bene ... discloses that the computing and control unit (26) can calculate the dialysance of the apparatus during the treatment session based on blood flow rate and/or dialysis liquid flow rate values sent to the control unit (see figure 1 & col. 4, line 33-col.6, line 51)." Final Office Action at p. 3.

It is respectfully submitted that Bene does not anticipate the present claims for at least the reason that Bene does not disclose, or even suggest, all of the limitations recited in amended claim 7. For instance, it is respectfully submitted that Bene fails to disclose, or even suggest, a means for determining in a first step at least one of a clearance and a dialysance during a dialysis treatment, at the at least one of the blood flow rate Q_b , the dialysis fluid flow rate Q_d , and the ultrafiltration rate Q_f determined by the first device, wherein the means for determining at least one of a clearance and a dialysance is a computer unit which is configured to determine in a subsequent step at least one of the clearance and the dialysance at the at least one of a blood flow rate $Q_b(t)$, a dialysis fluid flow rate $Q_d(t)$, and an ultrafiltration rate $Q_f(t)$, on the basis of, and without requiring additional measurements of, the at least one of the clearance and a dialysance initially determined at the at least one of a predetermined blood flow rate Q_b , a predetermined dialysis fluid flow rate Q_d , and a predetermined ultrafiltration rate Q_f , as recited in amended claim 7. In contrast, Bene describes that "[m]easurements are then taken in the dialysis liquid during the whole treatment session by means of the sensors 27." Col. 6, lines 45 to 47 (emphasis added). Bene also describes that "the signals delivered by the sensors 27 are supplied to the computing and control unit 26 which controls the artificial kidney according to the parameters which it calculates, such as certain characteristic values of the blood (the concentration of ionized substances, of bicarbonate for example) as well as the performance of the artificial kidney (dialysance, clearance for a given substance) and according to the data which are supplied to it by an operator prior to the treatment session, such as the duration T of the session, the flow rates of the blood Q_B and of the dialysis liquid

QD, the desired loss of weight WL, the desired concentration [A], [B], [C] of electrolytes A, B, C in the blood, and in particular, the desired clearance of urea KUR." Col. 5, line 65 to col. 6, line 11 (emphasis added). Furthermore, Bene states that "one programs the consecutive passing into the exchanger 1 of two volumes of dialysis liquid having different conductivities so as to measure ... four conductivity values CDi1, CDo1, CDi2, CDo2 ... from which the unit 26 can calculate the concentration CBi of ionized substances in the patient's blood at the inlet of the exchanger." Col. 6, lines 56 to 66 (emphasis added). Thus, in Bene, further measurements of the conductivity of the dialysis fluid at the inlet and the outlet of the exchanger are necessary in the case that one or more of the given values has changed. To the extent that Bene discloses that a clearance is calculated by previously-known rules of correspondence and extrapolation, e.g., col. 7, lines 19 to 26, Bene merely discloses that the rules of correspondence are used for calculating the clearance of urea on the basis of the dialysance for sodium rather than the dialysance and/or clearance throughout the course of the entire dialysance treatment for changed fluid rates on the basis of the clearance and/or dialysance initially determined in a first step at the previously given fluid rate values. Rather, Bene discloses a means for determining characteristics of blood that requires the taking of frequent measurements.

To anticipate a claim, each and every element as set forth in the claim must be found in a single prior art reference. Verdegaal Bros. v. Union Oil Co. of Calif., 814 F.2d 628, 631, 2 U.S.P.Q.2d 1051, 1053 (Fed. Cir. 1987). Furthermore, "[t]he identical invention must be shown in as complete detail as is contained in the ... claim." Richardson v. Suzuki Motor Co., 868 F.2d 1226, 1236, 9 U.S.P.Q.2d 1913, 1920 (Fed. Cir. 1989). That is, the prior art must describe the elements arranged as required by the claims. In re Bond, 910 F.2d 831, 15 U.S.P.Q.2d 1566 (Fed. Cir. 1990). As more fully set forth above, it is respectfully submitted that Bene does not disclose, or even suggest, all of the limitations recited in amended claim 7.

Additionally, to reject a claim under 35 U.S.C. § 102, the Examiner must demonstrate that each and every claim limitation is contained in a single prior art reference. See, Scripps Clinic & Research Foundation v. Genentech, Inc., 18 U.S.P.Q.2d 1001, 1010 (Fed. Cir. 1991). Still further, not only must each of the claim limitations be identically disclosed, an anticipatory reference must also enable a person having ordinary skill in the art to practice the claimed invention, namely the

inventions of the rejected claims, as discussed above. See, Akzo, N.V. v. U.S.I.T.C., 1 U.S.P.Q.2d 1241, 1245 (Fed. Cir. 1986). In particular, it is respectfully submitted that, at least for the reasons discussed above, the reference relied upon would not enable a person having ordinary skill in the art to practice the inventions of the rejected claims, as discussed above. Also, to the extent that the Examiner is relying on the doctrine of inherency, the Examiner must provide a "basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristics necessarily flows from the teachings of the applied art." See M.P.E.P. § 2112; emphasis in original; and see, Ex parte Levy, 17 U.S.P.Q.2d 1461, 1464 (Bd. Pat. App. & Inter. 1990). Thus, the M.P.E.P. and the case law make clear that simply because a certain result or characteristic may occur in the prior art does not establish the inherency of that result or characteristic. Accordingly, the anticipation rejection as to the rejected claims must necessarily fail for the foregoing reasons.

In summary, it is respectfully submitted that Bene does not anticipate claim 7.

As for claims 12 and 13, which depend from claim 7 and therefore include all of the limitations of claim 7, it is respectfully submitted that Bene does not anticipate these dependent claims for at least the same reasons given above in support of the patentability of claim 7.

III. Rejection of Claims 9 to 11 Under 35 U.S.C. § 103(a)

Claims 9 to 11 were rejected under 35 U.S.C. § 103(a) as unpatentable over Bene. It is respectfully submitted that Bene does not render obvious claims 9 to 11 for the following reasons.

The Final Office Action contends that "Bene disclosed the invention substantially as claimed," Final Office Action at p. 4, but admits that "Bene ... fails to disclose specifically that the computer calculates a diffusive component D_1 , effective blood flow Q_e (claim 9), the diffusive dialysance $D(Q_d(t))$ for any flow rate $Q_d(t)$ (claim 10), and the sum of the diffusive and convective dialysance $k(Q_d(t), Q_e, Of(t))$ or the clearance from the diffusive dialysance $D(Q_d(t), Q_e(t))$ according to their respective equations set forth in their respective claims." Final Office Action at p. 4. However, the Final Office Action contends that "since the computing and control unit of Bene computes values using formulas to calculate the dialysance based on

values received by other monitoring devices (for example the sensors), it clearly uses programmable software to perform the mathematical calculations [and that] the computing and control unit of Bene is clearly capable of being programmed with the required equations such that the control unit can calculate the diffusive component $D1$, effective blood flow Q_e (claim 9), the diffusive dialysance $D(Q_d(t))$ for any flow rate $Q_d(t)$ (claim 10), and the sum of the diffusive and convective dialysance $k(Q_d(t), Q_e, Of(t))$ or the clearance from the diffusive dialysance $D(Q_d(t), Q_e(t))$." Final Office Action at pp. 4 to 5. Thus, the Final Office Action concludes that "[i]t would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the computing and control unit of Bene to store desired equations to calculate diffusive component $D1$, effective blood flow Q_e (claim ()), the diffusive dialysance $D(Q_d(t))$ for any flow rate $Q_d(t)$ claim 10), and the sum of the diffusive and convective dialysance $k(Q_d(t), Q_e, Of(t))$ or the clearance from the diffusive dialysance $D(Q_d(t))$, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art." Final Office Action at p. 5.

As stated above, it is respectfully submitted that Bene does not disclose, or even suggest, all of the limitations recited in amended claim 7. For example, it is respectfully submitted that Bene does not disclose, or even suggest, a means for determining in a first step at least one of a clearance and a dialysance during a dialysis treatment, at the at least one of the blood flow rate Q_b , the dialysis fluid flow rate Q_d , and the ultrafiltration rate Q_f determined by the first device, wherein the means for determining at least one of a clearance and a dialysance is a computer unit which is configured to determine in a subsequent step at least one of the clearance and the dialysance at the at least one of a blood flow rate $Q_b(t)$, a dialysis fluid flow rate $Q_d(t)$, and an ultrafiltration rate $Q_f(t)$, on the basis of, and without requiring additional measurements of, the at least one of the clearance and a dialysance initially determined at the at least one of a predetermined blood flow rate Q_b , a predetermined dialysis fluid flow rate Q_d , and a predetermined ultrafiltration rate Q_f . as recited in amended claim 7.

In rejecting a claim under 35 U.S.C. § 103(a), the Examiner bears the initial burden of presenting a prima facie case of obviousness. In re Rijckaert, 9 F.3d 1531, 1532, 28 U.S.P.Q.2d 1955, 1956 (Fed. Cir. 1993). To establish prima facie obviousness, three criteria must be satisfied. First, there must be some

suggestion or motivation to modify or combine reference teachings. In re Fine, 837 F.2d 1071, 5 U.S.P.Q.2d 1596 (Fed. Cir. 1988). This teaching or suggestion to make the claimed combination must be found in the prior art and not based on the application disclosure. In re Vaeck, 947 F.2d 488, 20 U.S.P.Q.2d 1438 (Fed. Cir. 1991). Second, there must be a reasonable expectation of success. In re Merck & Co., Inc., 800 F.2d 1091, 231 U.S.P.Q. 375 (Fed. Cir. 1986). Third, the prior art reference(s) must teach or suggest all of the claim limitations. In re Royka, 490 F.2d 981, 180 U.S.P.Q. 580 (C.C.P.A. 1974). As indicated above, Bene does not disclose, or even suggest, all of the limitations recited in claim 7.

Moreover, it is respectfully submitted that the cases of In re Fine, supra, and In re Jones, 21 U.S.P.Q.2d 1941 (Fed. Cir. 1992), make plain that the Final Office Action's generalized assertions that it would have been obvious to modify or combine the reference do not properly support a § 103 rejection. It is respectfully submitted that those cases make plain that the Final Office Action reflects a subjective "obvious to try" standard, and therefore does not reflect the proper evidence to support an obviousness rejection based on the reference relied upon. In particular, the Court in the case of In re Fine stated that:

The PTO has the burden under section 103 to establish a *prima facie* case of obviousness. It can satisfy this burden only by showing some objective teaching in the prior art or that knowledge generally available to one of ordinary skill in the art would lead that individual to combine the relevant teachings of the references. This it has not done. . . .

Instead, the Examiner relies on hindsight in reaching his obviousness determination. . . . One cannot use hindsight reconstruction to pick and choose among isolated disclosures in the prior art to deprecate the claimed invention.

In re Fine, 5 U.S.P.Q.2d at 1598 to 1600 (citations omitted; italics in original; emphasis added). Likewise, the Court in the case of In re Jones stated that:

Before the PTO may combine the disclosures of two or more prior art references in order to establish *prima facie* obviousness, there must be some suggestion for doing so, found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. . . .

Conspicuously missing from this record is any evidence, other than the PTO's speculation (if it be called evidence)

that one of ordinary skill . . . would have been motivated to make the modifications . . . necessary to arrive at the claimed [invention].

In re Jones, 21 U.S.P.Q.2d at 1943, 1944 (citations omitted; italics in original).

That is exactly the case here since it is believed and respectfully submitted that the present Final Office Action offers no evidence whatsoever, but only conclusory hindsight, reconstruction and speculation, which these cases have indicated does not constitute evidence that will support a proper obviousness finding. Unsupported assertions are not evidence as to why a person having ordinary skill in the art would be motivated to modify or combine reference to provide the claimed subject matter of the claims to address the problems met thereby. Accordingly, the Office must provide proper evidence of a motivation for modifying or combining the references to provide the claimed subject matter.

More recently, the Federal Circuit in the case of In re Kotzab has made plain that even if a claim concerns a "technologically simple concept" – which is not the case here – there still must be some finding as to the "specific understanding or principle within the knowledge of a skilled artisan" that would motivate a person having no knowledge of the claimed subject matter to "make the combination in the manner claimed," stating that:

In this case, the Examiner and the Board fell into the hindsight trap. The idea of a single sensor controlling multiple valves, as opposed to multiple sensors controlling multiple valves, is a technologically simple concept. With this simple concept in mind, the Patent and Trademark Office found prior art statements that in the abstract appeared to suggest the claimed limitation. But, there was no finding as to the specific understanding or principle within the knowledge of a skilled artisan that would have motivated one with no knowledge of Kotzab's invention to make the combination in the manner claimed. In light of our holding of the absence of a motivation to combine the teachings in Evans, we conclude that the Board did not make out a proper prima facie case of obviousness in rejecting [the] claims . . . under 35 U.S.C. Section 103(a) over Evans.

In re Kotzab, 55 U.S.P.Q.2d 1313, 1318 (Fed. Cir. 2000) (emphasis added). Again, it is believed that there have been no such findings.

In summary, it is respectfully submitted that Bene does not disclose, or even suggest, all of the limitations recited in claim 7. As for claims 9 to 11, each of which ultimately depend from claim 7 and therefore include all of the limitations of claim 7, it is respectfully submitted that Bene does not render unpatentable these dependent claims for at least the same reasons given above in support of the patentability of claim 7. In re Fine, supra (any claim that depends from a non-obvious independent claim is non-obvious).

IV. Conclusion

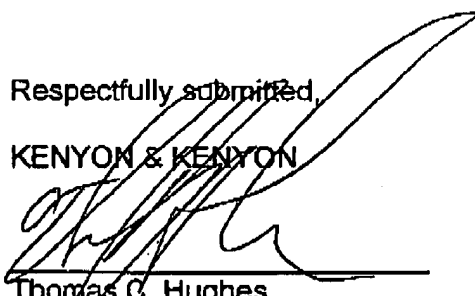
It is therefore respectfully submitted that all of the presently pending claims are allowable. All issues raised by the Examiner having been addressed, an early and favorable action on the merits is earnestly solicited.

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